K043082

NOV 2 3 2004

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SIGNUS Medizintechnik GMBH
Brentanostr 9, Alzenau, Germany D-63755
Phone: 49-6023 9166-0

Contact Person: Tracy L. Gray RN, BS, RAC

Date Prepared: November 5, 2004

Trade Name: The TOSCA® Anterior Cervical Plate System

Classification, Name and Number: Class II
21 CFR 888.3060 - Spinal Intervertebral Body Fixation Orthosis

Product Code: KWQ

Predicate Device(s): The subject device is equivalent to the following devices:

- The SCI Anterior Cervical Plate System (K990005), manufactured by Spinal Concepts, Inc.; and
- The EBI Anterior Plate System (K943694 - K002980) Manufactured by EBI, L.P.

Device Description: The TOSCA® Anterior Cervical Plate System consists of various sizes of bone plates and screws that are either fixed angle or variable angle. The screws are used to secure the plates to the vertebral bodies of the cervical spine though the anterior approach. The plates and screws are made from Titanium alloy Ti64A14V, are in conformance with ASTM F136-98, and are supplied non-sterile.

Intended Use: The TOSCA® Anterior Cervical Plate System is intended for anterior cervical fixation for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Functional and Safety Testing: Mechanical testing was conducted, and data collected, in accordance with ASTM 1717 to ensure the device performs according to specification, to verify that the device is able to withstand clinical loading and maintain mechanical integrity, and is suited for its intended purpose.

Conclusion: SIGNUS Medizintechnik GMBH considers the TOSCA® Anterior Cervical Plate System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 3 2004

Ms. Tracy L. Gray
Principal Consultant
Alquest, Inc.
4050 Olson Memorial Hwy, Suite 350
Minneapolis, Minnesota 55422

Re: K043082
Trade/Device Name: The TOSCA® Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: November 5, 2004
Received: November 8, 2004

Dear Ms. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: The TOSCA® Anterior Cervical Plate System

Indications For Use: The TOSCA® Anterior Cervical Plate System is intended for anterior cervical fixation for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, and trauma (i.e. fracture or dislocation), spinal stenosis, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043082